

Appl. No. 10/080,435
Amdt. dated 4 January 2006
Reply to Office Action of 4 October 2005

PATENT

REMARKS/ARGUMENTS

Claim 8 has been revised to expressly recite features found in the language of claim 1, from which claim 8 depends, and in claim 8 as filed. No change in claim scope is intended or believed to have occurred.

No new matter has been introduced, and entry of the above claims is respectfully requested.

INTERVIEW OF OCTOBER 20, 2005

Applicants thank Examiners S. Chunduru and J. Fredman for the courtesy of an in-person interview with the undersigned and the assignee's representative, N. Verona, who joined by telephone. Applicants particularly appreciate the fact that Examiner Fredman took time out of his busy schedule for the 30 minute interview.

Applicants further thank the examiners for the indication in the Interview Summary (Form PTOL-413) that the arguments presented during the interview were persuasive and that they should be included as part of a written response.

The arguments, which pertain to the alleged rejections based upon cited references, are presented below. Briefly, Applicants explained how a rejection based on a combination of teachings including Western blotting of proteins is too remote from the subject matter of the instant invention to support a *prima facie* case of obviousness.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 8-9 were rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for not setting "forth any steps involved in the method/process.... A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced."

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Applicants have carefully reviewed the statement of the rejection as well as the cited references. Applicants respectfully traverse because no *prima facie* case of obviousness has been presented.

As an initial matter, Applicants point out that claims 8 and 9 are dependent from claim 1, which is directed to a method with specifically recited acts. In accordance with well settled law, those acts are expressly present in the methods of claims 8 and 9 as if fully set forth. Thus the above quoted assertion of an absence of "steps" is misplaced.

Applicants respectfully submit that the question of indefiniteness must be viewed from the perspective of the skilled person, who, when provided with claims 1, 8, and 9, would recognize that the subject matter of claim 8 is simply where a plurality of binding agents (recited in claim 1), attached to a plurality of different nucleic acid molecules (also recited in claim 1), are used to bind a plurality of ligands so that the ligands may be detected by detection of the nucleic acid molecules attached to the binding agents. This is very clear from a simple comparison of the language of claims 1 and 8, and the mere recitation of the word "used" does not alter this fact. Claim 9 simply sets forth the further feature of the binding agents being antibodies. Accordingly, Applicants submit that no *prima facie* case of indefiniteness is present, and this rejection may be withdrawn for that reason alone.

Nevertheless, and in the interest of advancing prosecution without acquiescence to the instant rejection, Applicants have revised claim 8 to recite features found in the language of claim 1 and in claim 8 as filed. These features were express and/or inherent in both claims 1 and 8, and so there has been no alternation in claim scope. Applicants respectfully submit that with the revisions, this rejection is no longer applicable and may be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 1-8, 10-19 and 21 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Ornstein et al. (Clin. Cancer Res. 6:353-356, 2000) and Eberwine et al. (USP 6,255,060). Applicants have carefully reviewed the statement of the rejection as well as the cited references. Applicants respectfully traverse because no *prima facie* case of obviousness has been presented. As an initial matter, Applicants point out that Eberwine et al. (USP 6,255,060) claims

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priority as a "continuation-in-part" application of USP 5,922,553 (Eberwine et al.), which was previously asserted. The content relied upon from both patents appear to be essentially, if not actually, identical.

As discussed during the interview of October 20, 2005, Ornstein et al. describe a method where cells are isolated and then lysed and boiled in "2X SDS buffer" followed by separation on "4-20% tris-glycine nondenaturing gels" (see page 354, left column, first paragraph). After this gel electrophoresis, the separated proteins are transferred from the gels to nylon membranes and subjected to Western blotting with antibodies.

As admitted in the statement of the instant rejection, however, Ornstein et al. do not disclose contacting a cell containing sample with "a binding agent (antibody) attached to a detectable nucleic acid." Thus the instant rejection turns to Eberwine et al. for the discussion of using an antibody conjugated to a nucleic acid for detection of a ligand bound by the antibody.

But as pointed out during the interview, and based on Applicants' understanding of the rejection, a combination of the Eberwine et al. antibody with Ornstein et al. method would not result in the claimed invention because the Eberwine et al. antibodies would be used in place of the antibodies in the Ornstein et al. methods. This results in the (binding agent) antibodies not being used in the method until the end. This is in contrast to the instant claims, where the binding agent is contacted with a cell or tissue sample before any staining or isolation. Thus the use of the Eberwine et al. antibodies in the Ornstein et al. methods would not result in the claimed invention.

Applicants further point out that there is no basis to suggest that a person of ordinary skill in the art would be motivated to alternatively use the Eberwine et al. antibodies at the start of the Ornstein et al. method. In this case, the antibodies would be subjected to the same boiling conditions, which would simultaneously lyse the cells and separate the antibodies from their cognate ligands. How is the skilled person to proceed with this situation to detect ligands bound by the antibodies? Applicants respectfully submit that no motivation or guidance is present for such a radical combination and alteration in the methods of either Ornstein et al. or Eberwine et al.

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Applicants respectfully submit that the instant rejection is based on a combination of disclosures that is too far removed from the instantly claimed invention to support a *prima facie* case of obviousness. Accordingly Applicants respectfully submit that the instant rejection is misplaced and should be withdrawn.

As a final matter, Applicants point out that neither Ornstein et al. or Eberwine et al., nor a combination thereof, describes or suggests the use of a plurality of binding agents to detect a plurality of ligands as encompassed by claim 8. Accordingly, no *prima facie* case against claim 8 is present because all the features of the methods of claim 8 are not found in the cited references alone, or in combination.

Claims 9 and 20 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Ornstein et al. (Clin. Cancer Res. 6:353-356, 2000) and Eberwine et al. (USP 6,255,060) as applied above and further in view of Oku et al. (USP 5,789,165). Applicants have carefully reviewed the statement of the rejection as well as the cited references. Applicants respectfully traverse because no *prima facie* case of obviousness has been presented.

The statement of the rejection indicates that the inclusion of Oku et al. was for its disclosure relative to the use of a plurality of binding agents to detect a plurality of ligands bound by the binding agents.

Applicants' review of Oku et al., however, shows that it does not remedy any of the deficiencies noted above with respect to a combination of Ornstein et al. and Eberwine et al. Therefore, the failure to present a *prima facie* case, as explained above, is also present here because claims 9 and 20 are dependent, and so have all the features, of the claims rejected above.

Given that Oku et al. do not remedy the deficiencies of Ornstein et al. and Eberwine et al., this rejection is misplaced and may be properly withdrawn.

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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6100.

Respectfully submitted,


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